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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,171	02/04/2002	Sally Mossman	014058-013300US	8073
20350	7590	08/25/2004		
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER WANG, SHENGJUN	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,171

Applicant(s)

MOSSMAN ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/12/03&2/10/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) 1-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 90-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/17/03, 11/12/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 1-89 and 90-95 (all in part) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/12/03 and 2/10/04.

2. Applicant's election with traverse of group IX, claims 90-92 (all in part, formula 1a) in the reply filed on 11/12/03 is acknowledged. The traversal is on the ground(s) that group IX and group XI should be examined together because formula 1a and 1c all fall within the class AGP and are related. This is not found persuasive because the two groups of compounds are structurally distinct and have acquired separate status in the art.

3. The requirement is still deemed proper and is therefore made FINAL.

4. Applicants also traverse the restriction on the ground that groups IX and XII should be examined together as they related as subcombination and combination. In view the fact that immune potentiating agents are normally used with antigen in the art, the examiner found the traverse is persuasive. Therefore, groups IX and XII have been examined as one group

5. Applicants' election of the particular species of AGP, saponin, and antigen in paper submitted February 10, 2004 is acknowledged. Since applicants did not state whether the election was made with or without traverse, the election of species was considered made *without traverse*.

The claims have been examined insofar as they read on the elected invention and species.

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Claim Rejections 35 U.S.C. 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 90-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,113,918, IDS) in view of Kensil et al. (US 5,057,540), and in further view of applicants' own admission.

8. Johnson et al. teach that aminoalkyl glucosamine phosphates, including the particular elected AGP herein, are known as adjuvant, and immunoeffectors. Johnson further teaches that the adjuvants composition may be in various forms including oil-in-water or water-in-oil emulsions, liposome, etc; vaccine composition comprising the AGP and antigen. Johnson et al. also teach a method of using the AGP for enhancing the immune response of an animal. See, particularly, the abstract, columns 2-5, example 20 in column 42, and the claims.

9. Johnson et al do not teach expressly the employment of a combination of AGP and Quil A for enhancing the immune response.

10. However, Kensil et al. teaches that Quil A is known to be useful as immune adjuvant, which is useful for stimulating immune response, particularly co-administered with antigen. The adjuvant may be administered individually or admixed with other adjuvants to achieve the enhancements of the immune response to antigen, including those of tuberculosis. See, particularly, the abstract, column 6, line 54 to column 7, lines 40, and the claims.

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Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a composition comprising the two adjuvants herein, i.e., quil A and the particular AGP herein, and optionally further comprising antigen, such as those for tuberculosis.


A person of ordinary skill in the art would have been motivated to composition comprising the two adjuvants herein, i.e., Quil A and the particular AGP herein, and optionally further comprising antigen, such as those for tuberculosis because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus , the claimed invention which is a combination of two known adjuvants sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. As to the particularly amount of each active ingredients herein, note, the optimization of a result effective parameter, e.g., amounts of the active ingredients in a pharmaceutical composition, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. With respect to the particular antigen herein, note applicants acknowledged that such antigen was known in the art. See the example 1 herein at page 74. Using a known antigen properly is within the skill of artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571)272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

SHENGJUN WANG
PRIMARY EXAMINER


Shengjun Wang

August 17, 2004